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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TITLE:      Composition and method for treating  
                 Vulvodynia

INVENTORS:      W. Jerry Easterling  
                 William P. Fitch

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2 BACKGROUND OF THE INVENTION

3 1. Field of The Invention

4 The present invention relates to medical treatments  
5 pertaining to vulvodynia.  
6

7 2. Background Information

8 Vulvodynia is characterized by unexplained vulvar pain  
9 that can cause physical disability, sexual dysfunction,  
10 limitation of normal daily activities, and psychological  
11 difficulties.  
12

13 The problem often becomes chronic, lasting for years.  
14 There are four basic types of vulvodynia: (1) vulvar  
15 vestibulitis (2) dysesthetic vulvodynia (3) vulvar dermatoses  
16 and (4) cyclic vulvovaginitis. Many patients are misdiagnosed  
17 or not diagnoses at all. Pain is not always accompanied by  
18 visible tissue changes, thereby complicating an accurate  
19 diagnosis. Vulvar vestibulitis and dysesthetic vulvodynia are  
20 the most common.

21 The etiology of the disease is unknown. However, it has  
22 been hypothesized that viral, fungal and bacterial assaults,  
23 allergic reactions, and an autoimmune response to the body's  
own chemistry may play a role in the disease process.

1 Irritation of the muscles that support the uterus, bladder and  
2 rectum as well as irritation of the nerves of the vulva tissue  
3 may result in the painful symptoms associated with Vulvodynia.

4 Empirical evidence indicates that approximately fifteen  
5 percent of the adult female population may suffer from  
6 Vulvodynia at sometime during their lifetime. Approximately  
7 seventy percent of women with Vulvodynia are white, have fair  
8 complexion, and are of child bearing age. A study published  
9 in the Journal of Urology in May of 1997 suggested that ten  
10 percent of women with interstitial cystitis also have symptoms  
11 of Vulvodynia.

12 Many patients experience difficulty is walking,  
13 sensitivity to clothing touching the vaginal area, difficulty  
14 with sexual activities due to pain, difficulty in sitting for  
15 long periods, and mild to intense pain described as burning,  
16 stinging, or itching.

17 Treatments for vulvodynia include oral medications such  
18 as antihistamines, tricyclic antidepressants; topical  
19 estrogens; and anticonvulsants; physical therapy and  
20 biofeedback; Interferon intralesional injections; low  
21 oxalate diet; oral calcium citrate; laser therapy; and  
22 surgery. Laser and surgical treatment complications include  
23 hematoma, wound dehiscence, uneven healing, and stenosis of

1 the Bartholin's duct with cyst formation. There is no known  
2 cure for Vulvodynia.

3  
4 SUMMARY OF THE INVENTION

5 It is an object of the present invention to provide a  
6 novel medicament to be used for the treatment of Vulvodynia.

7 It is another object of the present invention to provide  
8 a novel medicament and unobvious medicament for the treatment  
9 of Vulvodynia, which medicament is more effective than  
10 existing means for treatment.

11 In satisfaction of these and related objectives,  
12 Applicant's present invention provides the vaginal application  
13 of a calcium channel blocker agent (preferably in suppository  
14 form) and associated methodology for use thereof, through the  
15 use of which Vulvodynia may be effectively, noninvasively,  
16 cost effectively, and painlessly treated.

17  
18 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

19 The preferred embodiment of the medicament of the present  
20 invention is a vaginal suppository which has demonstrated  
21 relief from the symptoms of Vulvodynia in as little as ten  
22 days of treatment.

1 In the preferred embodiment, the primary active  
2 ingredient of the vaginal suppository is Diltiazem  
3 Hydrochloride, USP, a benzothiazepine calcium channel blocker.  
4 However, it should be understood that other calcium channel  
5 blockers (topically applied, may provide similar relief.  
6 Others include Verapamil, a diphenylalkylamine,  
7 dihydropyridines, and the fast sodium inward channel  
8 inhibitor, Bepridil.

9 The preferred Diltiazem-based vaginal suppository  
10 formulation follows:

11 Diltiazem 50mg Vaginal Suppository	30 each
12 Diltiazem Hydrochloride, USP	1.50 Gm
13 Silica Gel, micronized	0.45 Gm
14 Base MBK (Fatty Acid)	32.85 Gm

15 Melt the Base MBK at 50 degrees Centigrade. Triturate the  
16 Diltiazem with the Silica Gel. Using a wire mesh strainer,  
17 sprinkle the powdered mixture into the melted base with  
18 stirring. Remove from heat and continue stirring until a  
19 uniform suspension exists. Pour into suppository shells and  
20 allow to cool at room temperature. Heat seal the open ends of  
21 the suppository shells. STORE IN REFRIGERATOR at 4 degrees  
22 Centigrade.

1           The recommended single dose of the Diltiazem Vaginal  
2           Suppository contains 50mg of Diltiazem and is contained in  
3           1.16 Gm of the preferred embodiment of the suppository.

4           Packaging in which the suppositories are dispensed to  
5           patients should be labeled with the following legend: STORE  
6           IN REFRIGERATOR.

7           The patient is to insert vaginally one suppository once  
8           or twice daily, depending on patient response as measured by  
9           the patient's physician. During treatment, the patient's  
10          progress should be evaluated by the physician at least every  
11          thirty days.

12          It should be noted that Diltiazem is commonly given  
13          orally to treat hypertension or cardiac arrhythmias. Patients  
14          should be counseled to report any side effect that could  
15          relate to blood pressure changes or noticeable heart rate  
16          changes. Any vaginal mucosa irritation should also be  
17          immediately reported.

18          It is unclear how the medicament of the present invention  
19          works to relieve the symptoms of Vulvodynia. The inventor  
20          believes that upon successful absorption of the Diltiazem into  
21          the vaginal mucosa, that the calcium channel blocking  
22          properties of the Diltiazem may exert an antivasoconstrictor  
23          activity or initiate a non-vascular process such as serotonin

1 release or serotonin and histamine receptor blockade. The  
2 inventor also believes that after repeated use of the  
3 medicament, that a tissue remodeling of damaged or scarred  
4 tissue may occur, resulting in a healthier tissue accompanied  
5 by resolution of symptoms. The tissue remodeling process  
6 consists of the calcium channel blocker medication initiating  
7 the production of collagenase within the diseased tissue which  
8 initiates the remodeling process while the drug also causes a  
9 reduction in the production of fibroblasts associated with the  
10 production of scar tissue.

11 The medicament of the present invention has also shown  
12 efficacy in the treatment of symptoms associated with  
13 Interstitial Cystitis when used vaginally once or twice a day.  
14 This indicates that the present medicament has application  
15 well beyond the treatment of Vulvodynia, and promises relief  
16 of symptoms in any disease of similar mechanisms or physical  
17 manifestations like those of Vulvodynia.

18 Various modifications of the disclosed embodiments, as  
19 well as alternative embodiments of the inventions will become  
20 apparent to persons skilled in the art upon the reference to  
21 the description of the invention. It is, therefore,  
22 contemplated that the appended claims will cover such  
23 modifications that fall within the scope of the invention.